REMARKS

Claims 20-40 currently appear in this application. Claim 41 has been cancelled as it is a duplicate of claim 24. The Office Action of December 10, 2007, has been carefully studied. These claims define novel and unobvious subject matter under Sections 102 and 103 of 35 U.S.C., and therefore should be allowed. Applicant respectfully requests favorable reconsideration, entry of the present amendment, and formal allowance of the claims.

Claims 20-24 and 39 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Coleman et al., WO 98/14209 in view of Boccia et al., *Eur. J. Pediatr.* (2001) **160**: 385-391.

This rejection is respectfully traversed. Claim 1 has been amended to recite that the composition is for treating enteric infections of *Candida albicans* in humans. Support for this amendment can be found in the specification at page 2, penultimate paragraph.

The Examiner alleges that passive immunization through administration of IgY antibodies in order to protect against enteric infections is well known within the field. In support of this allegation, the Examiner cites, *e.g.*, Coleman, Yokoyama, Ikemori, Zuniga and Peralta et al. However, it should be noted that the cited documents describe experiments

on mice, calves, piglets. None of these documents describes a successful experiment on humans.

Boccia was sent to a scientific paper for publication two years after the publication of the Coleman application, and also after publication of the documents cited by the Examiner in support of absorption of IgY. Boccia does not suggest any therapy for preventing enteric diseases in infants, only that increased hygienic measures should be taken and that infected patients should be isolated (see Table 3). Since this relates to potentially life-threatening conditions, it must be assumed that an article reviewing measures to prevent and treat enteric diseases lists all known effective therapies. This fact suggests that Boccia did not know about any preventive or therapeutic measures that were effective for humans. Boccia further states that the presented studies are based on data from epidemics between 1973 and 1999, *i.e.*, it had been known for a long time that *Enterobacter cloacae* causes enteric infections.

Coleman only discloses one experiment, which is carried out on mice, namely, Example 1. Coleman therefore does not present anything that goes beyond what is disclosed by previous articles in the field, *i.e.*, antibody therapies that are effective in test animals. Coleman does not present

any data that would lead one skilled in the art to make said antibodies useful for therapy of enteric infections in humans.

It is clear from the above that no effective treatment against enteric infections in humans has been disclosed before the conception of the present claimed invention or filing of the present application. Neither Coleman nor any other document cited herein can therefore be considered as making obvious the presently claimed composition.

Human antibodies have not been effective in the human alimentary canal because the antibodies are deactivated in the stomach because of the low pH in the stomach. One skilled in the art has therefore not been motivated to treat humans with antibodies against endotoxins of any kind, as long as the antibodies, such as IgY antibodies, have not been sufficiently stable in the human stomach to be effective.

The present inventors knew that no antibodies had been effective in therapy of enteric infections in humans. However, despite this fact, they surprisingly discovered that a therapeutic effect could be obtained from administering IgY antibodies against *Enterobacter cloacae* to prematurely born infants. Somehow, the deactivation of the antibodies did not occur. It appeared that this was because the pH of the stomach of premature infants is higher than in full-term

infants. When mixing these IgY antibodies with a protecting agent such as a buffering agent, a therapeutic result is achieved with other patient categories, such as adult patients.

Since no effective therapies have been developed, despite the fact that there is a great need for such therapies, the cause of enteric diseases has long been known, and many research teams have made a great effort to find effective therapies, it is respectfully submitted that the solution to this problem is not trivial, and that the present composition fulfills a long-felt need.

Studies have been made using anti-*Candida albicans* IgY antibodies, where the antibodies were administered orally to chemotherapy patients with good results. As noted under Results in the enclosed article by Wilhelmson et al., *Food and Agricultural Immunology*, 2005. **16(1)**:41-45, the patients treated with *Candida albicans* antibodies exhibited no clinical signs of any *Candida* infection after treatment with the antibodies as claimed herein.

Since oral and gastro-intestinal *Enterobacter cloacae* infections can now be treated with anti-*Enterobacter cloacae* IgY antibodies, one skilled in the art would recognize that this would also be the case for oral and gastro-intestinal *Candida albicans* infections.

Accordingly, it is likely that the anti-*Candida albicans* IgY antibodies would also be effective in treating enteric *Candida* infections if administered to prematurely born infants, or to other patients if a buffering agent is included in the composition. Therefore, it is respectfully submitted that the scope of the presently claimed would also include anti*Candida albicans* IgY antibodies.

Claim 41 is objected to under 37 CFR 1.75 because it is a duplicate of claim 24.

Accordingly, claim 41 has been cancelled.

In view of the above, it is respectfully submitted that the claims are now in condition for allowance, and favorable action thereon is earnestly solicited.

Respectfully submitted,

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